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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,465	02/10/2004	Shivshankar Sundaram	N9136	1376

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EXAMINER

LOPEZ, AMADEUS SEBASTIAN

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/775,465	Applicant(s) SUNDARAM ET AL.	
	Examiner Amadeus S. Lopez	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 9-20 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-14 is/are allowed.
- 6) ☒ Claim(s) 1, 7, 15, 16 and 23-27 is/are rejected.
- 7) ☒ Claim(s) 2-5 and 17-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. **Claim 7 is objected to** because of the following informalities: Applicant states that claim 7 is currently amended when in fact it no changes have been made.

Appropriate correction is required.

2. **Claim 15 is objected to** because of the following informalities: In the preamble of claim 15, the applicant states that "after the medication is dispensed by an inhaler external to the inhaler..." The examiner assumes that the second "inhaler" should be deleted and replaced with - - spacer - -. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 23, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5042467 to Foley.**

Art Unit: 3743

4. **With regards to claim 23**, what is taught and shown by Foley in Fig1-3 is a spacer for facilitating the delivery of a medication spray from a medication spray dispenser to the mouth of a patient, the spacer comprising: spray inlet means (20) to receive the medication spray (Fig. 1 and 2); a mouthpiece (30); spacer walls defining at least one internal chamber and further defining an unobstructed, linear conduit means fluidly connecting the spray inlet to the mouthpiece (when the valve shown in Fig. 3 is in the open position; Also within paragraph 14 of the instant application, the applicant discloses that "in one embodiment of the spacer, a unidirectional valve is provided proximate the mouthpiece.") means to generate spray recirculation zones functional to inhibit contact between the medication spray and the spacer walls (recirculation zones formed by the combination of external air entering air aperture 102 leading into the chamber and the wall formed by 22 adjacent to the outlet leading into the mouthpiece).
5. **With regards to claim 26**, what is taught and shown by Foley in Figs. 1-3 is a method of delivering a medication spray into the lungs of a patient using a spacer, the method comprising: directing the medication spray into a spray inlet end of the spacer (Fig. 3); using the medication spray and spacer geometry to generate high-pressure recirculation zones inside the spacer (recirculation zones formed by the combination of external air entering air aperture 102 leading into the chamber and the wall formed by 22 adjacent to the outlet leading into the mouthpiece); and using the high pressure recirculation zones and external airflow to direct the medication spray walls of the spacer and along a linear path out of a mouthpiece end of the spacer (Fig. 3).

6. **With regards to claim 27**, what is taught and shown by Foley in Figs. 1-3 is a method comprising delivering external air into the spacer through air inlets (102; paragraph 12) positioned downstream from the spray inlet.

7. **Claims 1, 7, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2004/0094148 to Lulla et al.**

8. **With regards to claim 1**, what is taught and shown by Lulla et al in Figs. 1 and 2 is a spacer (Fig. 1 and 2) for delivering a medication spray into the lungs of a patient, the medication spray dispensed by an inhaler into the spacer (paragraph 1), the spacer comprising: a first conical body (102) having a large diameter distal end (end at 104) and a small diameter proximal end (end at 106); a second conical body (101) having a large diameter distal end (end at 103) and a small diameter proximal end (end at 105); a mouthpiece (106) positioned at the proximal end (106) of the conical first body (Paragraph 18); a spray inlet (105) positioned at the distal end of the second conical body to receive a medication spray dispensed by an inhaler (paragraph 19); and the first conical body (102) further comprising a first internal chamber and the second body comprising a second internal chamber forming an unobstructed linear spray conduit having a continuous spray passage from the spray inlet to the mouthpiece.

9. **With regards to claim 7**, what is taught and shown by Lulla et al. in Figs. 1-4 is a spacer wherein the cross-sections of the first and second conical bodies are elliptical.

10. **With regards to claim 15**, what is taught and shown by Lulla et al in Figs. 1 and 2 is a spacer apparatus for transmitting medication to patients after the medication is

Art Unit: 3743

dispensed by an inhaler external to the inhaler, the spacer comprising: a mouthpiece (106; paragraph 18); a first chamber (within conical body 102), the first chamber having a proximal end (end at 106) connected to the mouthpiece (106); a second chamber (within conical body 101), the second chamber having a proximal end (end at 103) connected to a distal end (end at 104) of the first chamber; a spray inlet (105) connected to a distal end of the second chamber (end at 105), the spray inlet adapted to receive medication spray from an inhaler, and an unobstructed linear internal spray path defined from spray path defined from spray inlet to the mouthpiece (Fig. 2), through the first chamber and the second chamber.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication No. 2004/0094148 to Lulla et al in view of US Patent No. 5809996 to Alldredge.

12. With regards to claim 16, what is taught and shown by Lulla et al in Figs. 1 and 2 is a spacer with all the limitations of claim 16 with the exception of wherein at least a portion of the one of the first or second chambers is collapsible. What is taught and shown by Alldredge in Figs. 2, 7, and 9 is a spacer wherein the chamber shown is collapsible (abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the spacer taught by Lulla et al by making at least a portion of the one of the first or second chambers is collapsible as taught by Alldredge in order to decrease the size of the inhaler apparatus making it easier to store or transport in the pocket or bag.

13. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5042467 to Foley in view of US Patent Application Publication No. 2004/0094148 to Lulla et al

14. With regards to claim 24, what is taught and shown by Foley in Figs. 1-3 is the spacer with all the limitations of claim 24, with the exception of the spacer walls defining first and second internal chambers. What is taught and shown by Lulla et al. in Figs. 1 and 2 is a spacer with walls defining first and second internal chambers. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the spacer of Foley to include 2 separate pieces with walls defining two

separate internal chambers because when comprised of two separate chambers, the spacer apparatus can be easily cleaned.

15. **With regards to claim 25**, what is taught and shown by Foley in Figs. 1-3 is the spacer with all the limitations of claim 25 including the means for generating high-pressure recirculation zones (recirculation zones formed by the combination of external air entering air aperture 102 leading into the chamber and the wall formed by 22 adjacent to the outlet leading into the mouthpiece) comprising a closed chamber proximal to the spray inlet (20) and at least one air inlet (102) in the first internal chamber (16) downstream of the spray inlet to allow external air into the first internal chamber (16).

Allowable Subject Matter

16. Claims 2-5 and 17-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. Claims 9-14 are allowed.

Conclusion


18. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure. US 6435176, US 6026807, and US 5178138.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

Art Unit: 3743

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 4/25/06
Amadeus S Lopez
Examiner
Art Unit 3743
April 25, 2006

ASL


Henry Bennett
Supervisory Patent Examiner
Group 3700